REMARKS

This paper responds to the Office Action mailed February 28, 2006. Claims 39-83 were pending and under consideration in connection with the present application. In the present paper, claims 71 and 83 are amended, claims 77-79 are cancelled, and new claims 84 and 85 are presented for consideration. Thus, following entry of the present amendment, claims 39-76 and 80-85 will be pending and under consideration.

Applicants note with appreciation the withdrawal of the rejection of the claims as obvious under 35 U.S.C. § 103(a) and kindly thank the PTO for the same.

I. The Amendments to the Claims

In the present paper, claims 71 and 83 are amended, new claims 84 and 85 are added, and claims 77-79 are cancelled without prejudice to Applicants' right to pursue the cancelled subject matter in one or more related continuation, divisional, or continuation-in-part applications.

The amendments to claims 71 and 83 are fully supported by the application as filed and thus present no new matter. In particular, the amendment to claim 71 is supported, for example, in the specification at page 4, lines 13-23, and in claim 25 as filed. Claim 83 has been amended solely to correct a grammatical error.

Further, new claims 84 and 85 are fully supported by the application as filed and thus present no new matter. In particular, new claims 84 and 85 are supported, for example, in the specification at page 3, lines 23-25, page 4, lines 13-23, and page 10, line 23-33.

As shown above, both the amendments to the claims and the new claims find full support in the instant application as filed and thus present no new matter. Entry of the amendment to the claims is therefore respectfully requested pursuant to 37 C.F.R. § 1.111.

II. The Rejection of Claims 39-76 and 80-83 under the Judicially-Created Doctrine of Obviousness-Type Double Patenting Should be Withdrawn

Claims 39-83 stand rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly obvious variants of claims 1-58 of U.S. Patent No. 6,770,648 ("the '648 patent"). Further, claims 39-83 stand provisionally rejected under the same doctrine as allegedly obvious variants of claim 1 of copending U.S. Patent Application No. 10/956,251 ("the '251 application").

In response, Applicants respectfully submit that the rejection as applied to claims 77-79 is moot in view of the cancellation of such claims. Further, Applicants respectfully submit that no claim of the '648 patent provides motivation to select the specific subgenus of

compounds recited by claims 39-76 and 80-83.[1] As such, the ordinarily-skilled artisan would not regard the subject matter of claims 39-76 and 80-83 as obvious variants of any claim of the '648 patent.

A. The Legal Standard

Under the judicially-created doctrine of obviousness-type double patenting, a claim must be patentably distinct from a *claim* of an already issued patent or pending application. *See General Food Corp. v. Studiengesellshaft Kohle mbH*, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992; emphasis added). If the claim at issue defines more than an obvious variation of the patented or pending claim, it is patentably distinct and rejection of the claim under the doctrine of obviousness-type double patenting is improper. *Id.*

To establish a proper obviousness-type double patenting rejection, the Examiner must show that the claim at issue is a "mere variation" of the patented or pending claim that "would have been obvious to those of ordinary skill in the relevant art." *See In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986). In the analysis, the "patent disclosure may not be used as prior art;" instead, the Examiner must focus on the "subject matter that *has been protected*, not...something one may find to be disclosed by reading them" or the specification. *See General Food Corp.*, 23 U.S.P.Q.2d at 1846, quoting *In re Vogel*, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970) and *In re Boylan*, 157 U.S.P.Q. 370, 371 (C.C.P.A. 1968).

Moreover, a proper obviousness-type double patenting analysis parallels the obviousness analysis performed under 35 U.S.C. § 103(a). *See In re Braat*, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991) and M.P.E.P. § 804. Thus, arguments showing non-obviousness under 35 U.S.C. 103(a) may be made to show that a claim is not an obvious variant of a patented or pending claim. For example, Applicants may show that the claims at issue are not obvious variants of the patented claims by showing that such claims are not *prima facie* obvious variants of the patented claims. One way Applicants may show such non-obviousness is to show that the patented claims define a genus that does not suggest the species or subgenus recited by the claims at issue. *See In re Baird*, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994).

[1] Applicants note that claims 39-49 relate to a particular genus of compounds, while claims 50-60 relate to compositions comprising such compounds and claims 61-83 relate to methods of using such compounds. Thus, the compositions and methods of claims 50-83 each recite the genus of compounds recited by claims 39-49, and thus Applicants address claims 49-83 together.

B. No Claim of the '648 Patent Suggests Selection of the Subgenus Recited by Claims 39-76 and 80-83

None of the generic claims of the '648 patent suggest the subgenus of compounds recited by claims 39-76 and 80-83, as none of the '648 patent's claims provides the specific motivation needed to select the particular substituents recited by claims 39-76 and 80-83. *See In re Baird*, 29 U.S.P.Q.2d at 1552. Applicants note that the PTO has referenced Table 24 of the '648 patent as depicting compounds within the presently-claimed subgenus. While Applicants do not dispute that the presently claimed compounds are encompassed within the genera claimed by the '648 patent, Applicants respectfully remind the PTO that the specification of the '648 patent disclosure cannot be used to construct the obviousness-type double patenting rejection. In particular, Table 24 **cannot** be used to provide suggestion or motivation to select the substituents of the presently claimed genus. *See In re Kaplan*, 229 U.S.P.Q. at 683. Rather, only the *claims* of the '648 patent can be used in this analysis, none of which provide any motivation to select the *particular* substituents necessary to construct the specific subgenus recited by claims 39-76 and 80-83. *See In re Baird*, 29 U.S.P.Q.2d at 1552.

The Federal Circuit's discussion in *In re Kaplan* is instructive on this point. In this case, the Board of Patent Appeals and Interferences upheld an obviousness-type double patenting rejection of a method claim reciting a particular mixture of solvents over a patented claim that recited an "organic solvent." No claim of the patent further specified that the method should be performed with a mixture of solvents or with any particular mixture of solvents. However, the specific mixture recited by the rejected claim was disclosed in the specification of the patent that formed the basis of the double patenting rejection. In reversing the Board, the Federal Circuit pointed out that, notwithstanding the suggestion in *In re Vogel* that the portions of the specification that support a claim could be used to understand the scope of a claim, the "organic solvent' recited by the patent claim had adequate support *apart* from the specific mixture recited by the claim under examination. *See In re Kaplan*, 229 U.S.P.Q. at 683.[2]

Similarly, the genus of compounds recited by the claims of the '648 patent is supported by more than 300 specific species other than those presented in Table 24. Accordingly, Applicants respectfully submit that focusing on the compounds of Table 24 to

[2] For the PTO's convenience, a copy of the Federal Circuit's opinions in *In re Kaplan* and *In re Baird* is attached to this response as Exhibits 1 and 2, respectively.

the exclusion of all the other compounds disclosed in the '648 patent improperly treats the '648 patent disclosure as though it were prior art, as was specifically rejected in *In re Kaplan*.

Further, no claim of the '648 patent provides any express motivation to select the members of the claimed subgenus of compounds from the genera defined by these claims. The '648 patent claims compounds that have PPARγ modulatory activity, but no claim is drawn to a particular compound taught to have such PPARγ modulatory activity. As such, the claims of the '648 patent provide no motivation to the ordinarily-skilled artisan to select the particular substituents necessary to construct the presently-claimed subgenus of compounds from the genera defined by the '648 patent's claims. *See In re Baird*, 29 U.S.P.Q.2d at 1552. In view of this absence of suggestion or motivation, the PTO cannot establish that claims 39-76 and 80-83 are *prima facie* obvious variants of the claims of the '648 patent.

C. The Provisional Rejection of Claims 39-76 and 80-83 as Obvious Variants of Claim 1 of the '251 Application Should Be Withdrawn

Claims 39-83 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of the '251 application. Without agreeing to the propriety of the rejection, Applicants believe that this provisional rejection is the last remaining issue prior to allowance of claims 39-76 and 80-83. Further, Applicants believe the rejection of claims 77-79 is moot in view of the cancellation of such claims. As such, Applicants respectfully request that the provisional rejection of claims 39-76 and 80-83 be withdrawn, and that the issue of double patenting between the present claims and those of the '251 application be considered, if proper, during prosecution of the '251 application. *See* M.P.E.P. § 804 I.B.

III. The Rejection of Claims 39-76 and 80-83 as Invented by Another under 35 U.S.C. § 102(f) Should be Withdrawn

Claims 39-83 stand rejected under 35 U.S.C. § 102(f) over the '648 patent. In particular, the PTO contends that the same subject matter claimed in the present application is also claimed in the '648 application. Thus, according to the PTO, it is unclear who are the proper inventors for the instant invention.

Applicants respectfully submit that the inventions claimed in the '648 patent and in the instant application are directed to patentably distinct subject matter, in that, for example, claim 39 relates to a specific subgenus of compounds that is not disclosed in the '648 patent. In Applicants' view, conception of this distinct subgenus of compounds constitutes an invention independent from the conception of the much larger, broad genus of compounds

recited by, for example, claim 1 of the '648 patent. As such, Applicants believe there is no reason that the inventorship of the '648 patent and the instant application should necessarily be identical.

In addition, Applicants submit herewith a Petition to Correct Inventorship under 37 C.F.R. § 1.48(b) to delete Jonathan B. Houze as an inventor of the invention defined by the claims as presently pending. Applicants hereby state, keeping in mind the duty of good faith and candor imposed by 37 C.F.R. § 1.56, that the five remaining inventors are the true and correct inventors of the invention presently claimed in the instant application, and, further, that the instantly claimed invention was not derived from the invention claimed in the '648 patent.

Accordingly, Applicants respectfully submit that the rejection of claims 39-76 and 80-83 under 35 U.S.C. § 102(f) should be withdrawn.

IV. The Rejection of Claims 71-83 as Failing to Comply with the Written Description Requirement of 35 U.S.C. § 112, First Paragraph Should be Withdrawn

Claims 71-83 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. In particular, the PTO argues that the instant specification does not describe a sufficient nexus between modulation of the PPARγ receptor and useful treatment of a disease or condition. Thus, according to the PTO, the instant application does not describe a method of treating or preventing a condition or disorder mediated by PPARγ.

Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, Applicants have amended claim 71 to recite specific PPARγ-mediated conditions or disorders. Applicants believe that the instant application demonstrates Applicants' possession of the method presently recited by claims 71-76 as shown above. *See Moba, B.V. v. Diamond Automation, Inc.* 66 U.S.P.Q.2d 1429 (Fed. Cir., 2003). As such, Applicants respectfully submit that the rejection of claims 71-79 is moot in view of the amendment to claim 71 and cancellation of claims 77-79 and therefore respectfully request its withdrawal.

With regard to the rejection of claims 80-83 for lack of written description, Applicants respectfully traverse. Applicants respectfully submit that claims 80-83 are drawn to a method for *modulating* a PPARγ receptor with the recited genus of compounds, not a method of treating or preventing a condition or disorder mediated by the PPARγ receptor. Applicants believe that such methods are fully supported by the application as filed, particularly by

Example 600, which demonstrates that illustrative compounds 40-50 can bind the PPARγ receptor and compete with a PPARγ ligand for binding. Accordingly, Applicants respectfully submit that the instant application as filed demonstrates Applicants' possession of the methods recited by claims 80-83. *See Moba, B.V. v. Diamond Automation, Inc.* 66 U.S.P.Q.2d 1429 (Fed. Cir., 2003).

V. The Rejection of Claims 71-83 as Failing to Comply with the Enablement Requirement of 35 U.S.C. § 112, First Paragraph Should be Withdrawn

Claims 71-83 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the PTO argues that the instant specification does not describe a sufficient nexus between modulation of the PPARγ receptor and useful treatment of a disease or condition. Thus, according to the PTO, undue experimentation would be required to treat or prevent a condition or disorder mediated by PPARγ.

Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, Applicants have amended claim 71 to recite specific PPARγ-mediated conditions or disorders. Applicants believe that the present application demonstrates that the skilled artisan could use the recited genus of compounds in the methods of claims 71-76 for treating such PPARγ-mediated conditions or disorders without undue experimentation. *See In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

In particular, Example 600 of the instant application demonstrates that, for example, each of compounds 40-50 compete with a PPARγ receptor ligand with an IC_{50} value less than 10 μM, and, further, all but one of the claimed compounds exhibit an IC_{50} value less than 1 μM. Thus, one skilled in the art would recognize from the present application that at least 10 compounds within the genus recited by claims 71-76 and 79-83 can bind the PPARγ receptor with sub-micromolar affinity.

Moreover, Applicants respectfully invite the PTO's attention to Exhibit 3, Campbell, 2005, *Curr. Mol. Med.* 5(3):349-63, discussing the therapeutic utility of modulating the PPARγ receptor. In particular, this review article discusses the use of thiazolidinediones, potent PPARγ receptor modulators, to treat an array of conditions, including non-insulin dependent diabetes mellitus, obesity, hypercholesterolemia, hyperlipidemia, dyslipidemia, hypertriglylceridemia, hyperglycemia, insulin resistance, hyperinsulinemia, and atherosclerosis. Accordingly, Applicants respectfully submit that one skilled in the art would recognize, based on Applicants disclosure and the knowledge of the art in general, that PPARγ receptor modulators such as those recited by claims 71-76, could be used to treat non-

insulin dependent diabetes mellitus, obesity, hypercholesterolemia, hyperlipidemia, dyslipidemia, hypertriglylceridemia, hyperglycemia, insulin resistance, hyperinsulinemia, and atherosclerosis without undue experimentation.

With regard to claims 80-83, Applicants respectfully submit that such claims are drawn to methods of modulating PPARγ, not a method of treating a condition or disorder mediated by PPARγ. Applicants believe that one skilled in the art, following the disclosure of the present application, can practice the full scope of the methods of claims 80-83 without undue experimentation. In particular, as discussed above, Example 600 shows that illustrative compounds 40-50 can bind the PPARγ receptor and compete with a PPARγ receptor ligand for binding. As such, Applicants respectfully submit that one skilled in the art could use such compounds to modulate PPARγ with no more than routine experimentation. *See Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982).

Finally, with regard to claims 77-79, Applicants believe the rejection is moot in view of the cancellation of such claims.

Accordingly, Applicants respectfully submit that claims 71-76 and 80-83 comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, and therefore that the rejection of such claims on such basis should be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance.

Applicants believe that no fee is due in connection with this response beyond the fees associated with the Petition for Extension of Time. Should an additional fee be required, the Commissioner is hereby authorized to charge any such required fee(s) to Deposit Account No. 50-0487, referencing order number T00-014-3. A copy of this sheet is enclosed for such purpose.

By his signature appearing below, the Undersigned hereby represents that he is authorized by Amgen Inc. to submit this paper pursuant to 37 C.F.R. § 1.34.

Respectfully submitted,

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